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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,346	07/24/2001	Jian Ni	PF199D2	4955

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HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/27/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/911,346	NI ET AL.	
	Examin r	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-127* is/are pending in the application.

4a) Of the above claim(s) *21-28,53-60,95,96,126 and 127* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,29-31,34-52,60-62,65-83,92-94,97-115,124 and 125* is/are rejected.

7)☒ Claim(s) *32,33,63,64,95,96,126 and 127* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *11* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-20, 29-52, 61-83, 92-115, 124-127 are under consideration by the Examiner. Claims 21-28, 53-60, 84-91, 116-123 are drawn to a non-elected invention.

The indicated allowability of claims 1-17, 29-49, 61-64 is withdrawn.

Claim rejections-35 USC § 112, second paragraph

2. Claim 92 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 92, line 5 is rejected as vague and indefinite because it recites the ATCC Deposit No. 97103 rather than the ATCC Deposit No. 97157.

Claim rejections-35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 8, 9, 10, 12, 16, 17, 29-31, 34, 36, 40-42, 44, 48-49, 61-62, 65-66, 68, 72-74, 79-80, 92-93, 94, 97, 99, 103-105, 107, 111-112, 124-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Shau et al. (US Pat No. 5, 250,295) in light of Shau et al. (US Pat No. 5, 610,286).

Shau et al. disclose an antibody exhibiting specificity to NKEF (see column 6, lines 59-68; column 7, lines 1-7). A copy of the comparison of SEQ ID NO:2 (SEQUENCE COMPARISON 'A') of the NKEF C protein of the instant invention to which the claimed antibodies are drawn, and the amino acid sequence of the NKEF protein in the reference to

which the antibody is drawn, is enclosed at the end of this office action. Therefore, the antibody disclosed in the reference meets the limitations of the instant claims.

Shau et al. (US Pat No. 5, 610,286) reference is being relied upon because it teaches the amino acid sequence of NKEF C protein (see SEQ ID NO:2, column 14, lines 22-30), the amino acid sequence being an inherent characteristic of the protein. Normally, only one reference is used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple reference s has been held to be proper when the extra references are cited to prove that the characteristic not disclosed in the primary reference is an inherent characteristic of the thing taught in the primary reference (see MPEP. 2131.01). "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the instant case, the combination of the Shau et al references shows that the antibody disclosed against a specific NKEF protein in the Shau et al '295 reference, anticipates the instant claims, because the reference protein is 68.8% identical to the instant protein of SEQ ID NO:2. Therefore, the antibodies of the Shau et al reference meets the limitations of an antibody as recited in instant claims 8-9.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4a. Claims 3, 11, 35, 43, 67, 75, 85, 98, 106, 117 are rejected under 35 U.S.C. § 103 as being unpatentable over Shau et al (U.S. Pat No. 5,250,295) in view of Lerner (1982), and Harlow et al. (1988).

Shau et al. discloses an antibody to NKEF as set forth above in para 3. Shau et al. fail to disclose monoclonal antibodies to the NKEF protein.

Lerner teaches the production of antibodies from known polypeptides, wherein the antibody can have predetermined specificity and in addition can be of a single specificity (i.e. a monoclonal) (see abstract, page 592; and first paragraph). Lerner also teaches that antibodies made against a predetermined peptide, are useful in studying the protein conformation of the intact protein from which the immunizing peptide was cleaved from (column 2, page 594, last 8 lines on page). Further, Harlow et al. teach that peptides of six residues in length will

consistently elicit antibodies that bind to the original protein (page 76, third paragraph, especially lines 21-22).

Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to use the amino acid sequences taught by Shau et al., to produce monoclonal antibodies with a predetermined specificity as taught by Lerner with the expectation that the large quantities of monoclonal antibodies made against the NKEC proteins would be useful in determining the location of the NKEF protein within the cell or to be used in animal model immunotherapy.

4b. Claims 5-7, 13-15, 37-39, 45-47, 69-71, 76-78, 87-89, 100-102, 108-110, 119-125 are rejected under 35 U.S.C. § 103 as being unpatentable over Shau et al (U.S. Pat No. 5,250,295) in view of Queen et al. (U.S. Pat No. 5,530,101).

Shau et al. discloses an antibody to NKEF as set forth above in para 3. Shau et al. fail to disclose chimeric, single chain and Fab fragments to the NKEF protein.

Queen et al., (column 17, lines 31-43) teaches the production of antibody fragments, including the Fab fragment, and the production of chimeric and single chain antibodies (column 11, 52-65; 58-67).

Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to use the amino acid sequences taught by Shau et al., to produce antibody fragments, and single chain and chimeric antibodies to the NKEC protein as taught by Queen et al. The motivation for doing so would have been that these antibodies (Queen et al., column 20, lines 23-24) have the advantage of being used for diagnostic purposes. Queen

et al., (column 20, lines 16-19) also discloses that antibody fragments, including the Fab fragment can be used as a delivery component of an immunotoxin.

4c. Claims 18-20, 50-52, 81-83, 100-102, 113-115, are rejected under 35 U.S.C. § 103 as being unpatentable over Shau et al (U.S. Pat No. 5,250,295) in view of Lerner (1982) and Harlow et al. (1988) as applied to claims 3, 11, 35, 43, 67, 75, 85, 98, 106, 117 above, and further in view of Sevier et al. (1981).

The disclosure of Shau et al. in view of Lerner (1982) and Harlow et al. (1988) has been set forth above (see paragraph 4a). However, Shau et al. (1994) in view of Lerner (1982) and Harlow et al. (1988) do not explicitly teach the production of monoclonal antibodies using hybridomas.

Sevier et al. is a general and broad teaching which discloses the production of monoclonal antibodies against known antigens, including hybridomas producing the monoclonal antibodies (page 1797, column 2, first paragraph) and that monoclonal antibodies are more homogenous, specific and more easily available than polyclonal antibodies (see abstract, lines 5-9).

Therefore, it would have been prima facie obvious at the time the invention was made to take the antigen (NKEF) as taught by Shau et al., and make antibodies as taught by Lerner, and Harlow et al., and it would also be prima facie obvious to make hybridomas to produce monoclonals as taught by Sevier et al., because Sevier et al. teach that the advantages of using monoclonal antibodies include homogeneity, specificity and are more easily available than polyclonal antibodies and because the use of hybridomas (cell lines generating monoclonal antibodies) provides a easily replenishable source of a highly selective antibody.

Conclusion

Claims 32-33, 63-64, 95-96, 126-127 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
August 25, 2003